

### **REMARKS**

The present amendment is in response to a Notice of Non-Compliant Amendment dated July 2, 2009, wherein it was noted that claim 1 was amended in the April 20, 2009 Response to include a comma at line 3 without the proper marking. In this response, claim 1 has been corrected to include the proper marking for the inserted comma. In all other respects, this response is identical to that submitted April 1, 2009.

Reconsideration of this application is respectfully requested.

Claim 1 has been amended to clarify that the antigen in component (ii) is not *Mycobacterium w* and/or constituent(s) thereof. Support for this amendment can be found throughout the specification at, e.g., pages 16-18. Claims 3, 8, 9, and 22 have been amended to correct clerical errors. Claims 27 and 28 have been cancelled without prejudice or disclaimer. No new matter has been added by way of this amendment. Claims 1-26 and 29 are pending and at issue.

### **Claim Objection**

The Examiner has objected to claims 3, 8, and 9 because the term “*Mycobacterium w*” is not italicized. Claims 3, 8, and 9 have been amended as suggested by the Examiner so that italic type is used.

### **Anticipation Rejection**

Claims 1-17, 22-26, and 29 have been rejected under 35 U.S.C. §102(b) as anticipated by WO 2003/049667 (“Khamar”), or alternatively as anticipated by WO 2003/075825 (“Khamar 2”). Both references are cited by the Examiner for teaching compositions of whole *Mycobacterium w*.

See June 25, 2008 Office Action at page 7. According to the Examiner, the rejected claims do not restrict the source of the antigen, and are thus encompassed by the cited art because *Mycobacterium w* may serve as the antigen and the adjuvant.

In order to advance prosecution, claim 1 has been amended for clarification to expressly recite that the antigen is not *Mycobacterium w*. Support for this amendment can be found throughout the specification at, e.g., pages 16-18.

Applicants respectfully submit that the pending claims are not anticipated by the prior art because, *inter alia*, neither Khamar nor Khamar 2 disclose a composition wherein *Mycobacterium w* is used in combination with an antigen. In the present invention, *Mycobacterium w* serves as an adjuvant to augment the specific antigen-associated immune response of the antigen. See the pending claims and specification at, e.g., page 3 (lines 22-26), and pages 16-18.

As disclosed in the specification and also generally appreciated in the field of the invention, an adjuvant acts to enhance the immunogenicity of an antigen. See specification at, e.g., page 3, lines 22-26. Applicants have demonstrated that *Mycobacterium w* enhances the immunogenicity of several disease-specific antigens including, cancer antigen Ca-19.9, influenza antigen Vaxigrip, and hepatitis A antigen Havrix. See the specification at, e.g., pages 16-18. The surprising utility of *Mycobacterium w* as an adjuvant was not appreciated in the prior art and the cited references are completely silent regarding the use of *Mycobacterium w* in conjunction with any immunogenic agents.

In view of the foregoing, claims 1-17, 22-26, and 29 are not anticipated by Khamar or Khamar 2. Therefore, Applicants respectfully request that this rejection be withdrawn.

**Indefiniteness Rejection**

Claim 18 has been rejected as indefinite for being dependent on a rejected claim. In view of the arguments set forth above, Applicants respectfully submit that claim 1, from which claim 18 depends, is allowable and, therefore, request that this rejection be withdrawn.

**Conclusion**

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered, and that the pending claims be allowed and the case passed to issue.

If there are any other issues remaining that the Examiner believes can be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Dated: July 13, 2009

Respectfully submitted,

By 

Jay P. Lessler

Registration No.: 41,151

DARBY & DARBY P.C.

P.O. Box 770

Church Street Station

New York, New York 10008-0770

(212) 527-7700

(212) 527-7701 (Fax)

Attorneys/Agents For Applicant